

REMARKS

THE AMENDMENTS TO THE CLAIMS:

Claim 1 has been amended to clarify that the invention relates to an anastomosis stent comprised of a material that is resorbable by the patient in about a few minutes up to about 90 days. The conjugate material is selected from the group consisting of: frozen physiologic saline; polyethylene glycol chemically conjugated to a naturally occurring compound; and a conjugate of collagen and a synthetic hydrophilic polymer. This is amply supported, e.g., on page 18, line 1, to page 24, line 9. In addition, this is supported by claims 25, 28, and 38 as originally filed.

Claims 26, 27 and 37 have been canceled in order to eliminate redundancy introduced as a result of the above amendment to the claims. Similarly, claims 28, 33, 35, 36 and 38 have been amended recite proper dependencies.


Claims 18, 34, 41, 42, 49, 70, 94 and 96 have been amended to correct minor typographical errors. Thus, no new matter has been introduced, and entry of these amendments is proper. For the Examiner's convenience, pending claims upon entry of the amendment is listed in Appendix B.

THE INFORMATION DISCLOSURE STATEMENT:

Applicants are submitting an Information Disclosure Statement and request that the references disclosed therein be made of record with respect to the present application.

If the Examiner has any questions concerning this communication, she is welcome to contact the undersigned attorney at (650) 330-0900.

Respectfully submitted,

By:  _____

Louis L. Wu
Registration No. 44,413

REED & ASSOCIATES
800 Menlo Avenue, Suit 210
Menlo Park, California 94025
(650) 330-0900 Telephone
(650) 330-0980 Facsimile
F:\Document\2500\2518\preliminary amendment.doc

APPENDIX A
(REDACTED CLAIMS INDICATING AMENDMENTS MADE)

1. (Amended) An anastomosis stent for insertion into an opening in a lumen of a vessel or tissue of a patient, comprising:

- a first terminus;
- a second terminus;
- an opening at each terminus; and
- a primary lumen providing fluid communication between the openings at the first and second termini,

wherein at least one of the first and second termini is sized to be inserted into an opening in a vessel of a patient, and the stent is comprised of a ~~non-polyglycolic acid~~ material that is resorbable by the patient in about a few minutes up to about 90 days and that is selected from the group consisting of: frozen physiologic saline; polyethylene glycol chemically conjugated to a naturally occurring compound; and a conjugate of collagen and a synthetic hydrophilic polymer.

18. (Amended) The stent of claim 17, wherein the primary and intersecting lumens intersect at a point closer to the first terminus than to the second terminus.

28. (Amended) The stent of claim ~~27~~1, wherein the material ~~polyethylene glycol-~~ polyethylene glycol ~~containing compound comprises a~~ is ~~that is~~ chemically conjugated to ~~with~~ a naturally occurring compound.

33. (Amended) The stent of claim ~~27~~28, wherein the naturally occurring compound is a polysaccharide.

34. (Amended) The stent of claim ~~32~~33, wherein the polysaccharide is selected from the group consisting of hyaluronic acid, cyclodextrin, hydroxymethylcellulose, cellulose ether, and starch.

35. (Amended) The stent of claim 2728, wherein the naturally occurring compound is a glycosaminoglycan or a proteoglycan.

36. (Amended) The stent of claim 2728, wherein the polyethylene glycol has a molecular weight of about 100 to about 20,000 daltons.

38. (Amended) The stent of claim 371, wherein the ~~collagenic~~ material ~~is~~ comprises a conjugate of collagen that is chemically conjugated to and a synthetic hydrophilic polymer.

41. (Amended) A method of anastomosis comprising the ~~step~~steps of:

(a) inserting the first terminus of the stent of claim 1 though an aperture into the cavity of a physiologically functioning vessel of a patient, and the second terminus of the stent into a conduit, such that an interface is formed between the vessel and the conduit about the aperture; and

(b) attaching the vessel to the conduit at the interface.

42. A method of anastomosis comprising the ~~step~~steps of:

(a) inserting the first and second termini of the stent of claim 17 ~~through in~~into a physiologically functioning vessel of a patient, and the third terminus of the stent into a bypass conduit, such that an interface is formed between the vessel and the bypass conduit about the aperture; and

(b) attaching the vessel to the bypass conduit at the interface.

49. (Amended) The method of claim 48, wherein the polyethylene glycol is selected from the group consisting of polyethylene glycol di-succinimidyl glutarate, pentaerythritol polyethylene glycol ether tetra-succinimidyl glutarate, pentaerythritol polyethylene glycol ether tetra-succinimidyl glutarate, polyethylene glycol mono-succinimidyl succinate, polyethylene glycol mono-succinimidyl propionic acid, polyethylene glycol mono-succinimidyl succinamide, polyethylene glycol di-succinimidyl succinamide, polyethylene glycol di-epoxide, polyethylene glycol di-isocyanate, polyethylene glycol di-carbonyldiimidazole, pentaerythritol polyethylene glycol ether tetra-maleimidopropionamide, pentaerythritol polyethylene glycol ether tetra-

malimidopropionate, polyethylene glycol di-amine, diglycero polyethylene glycol ether tetra-amine, pentaerythritol polyethylene glycol ether tetra-amine, polyethylene glycol di-sulfhydryl, pentaerythritol polyethylene glycol ether tetra-sulfhydryl, pentaerythritol polyethylene glycol ether, diglycerol poly(ethylene glycol) ether, combinations thereof, and copolymers thereof.

70. (Amended) The plug of claim 5469, wherein the hydrophilic compound comprises a polyethylene glycol-containing compound.

94. (Amended) A sutureless method of anastomosis comprising the steps of:

(a) providing a stent comprising a first terminus, a second terminus, a third terminus, and an opening at each terminus that fluidly communicate with each other through the interior of the stent, wherein the stent is comprised of a non-polyglycolic acid material that is resorbable by a patient in up to about 90 days;

(b) inserting the first and second termini of the stent through an aperture into a cavity of a physiologically functioning vessel of a patient, and the third terminus of the stent into a bypass conduit, such that an interface is formed between the vessel and the ~~by-pass~~ bypass conduit about the aperture; and

(c) applying a tissue sealant at the interface to attach the conduit to the vessel.

96. (Amended) A sutureless method of anastomosis comprising the steps of:

(a) providing a stent comprising a first terminus, a second terminus, a third terminus, and an opening at each terminus that fluidly communicate with each other through the interior of the stent, wherein the stent is comprised of material that is resorbable by a patient in up to about 90 days;

(b) inserting the first and second termini of the stent through an aperture into a cavity of a physiologically functioning vessel of a patient, and the third terminus of the stent into a bypass conduit, such that an interface is formed between the vessel and the ~~by-pass~~ bypass conduit about the aperture; and

(c) applying a tissue sealant at the interface to attach the conduit to the vessel such that the interface exhibits a tensile strength of at least about 1.3N/cm^2 .

APPENDIX B
(PENDING CLAIMS UPON ENTRY OF AMENDMENT)

1. An anastomosis stent for insertion into an opening in a lumen of a vessel or tissue of a patient, comprising:

a first terminus;
a second terminus;
an opening at each terminus; and
a primary lumen providing fluid communication between the openings at the first and second termini,

wherein at least one of the first and second termini is sized to be inserted into an opening in a vessel of a patient, and the stent is comprised of a material that is resorbable by the patient in about a few minutes up to about 90 days and that is selected from the group consisting of: frozen physiologic saline; polyethylene glycol chemically conjugated to a naturally occurring compound; and a conjugate of collagen and a synthetic hydrophilic polymer.

2. The stent of claim 1, wherein the primary lumen is substantially straight.

3. The stent of claim 1, wherein the primary lumen is curved, bent, or both.

4. The stent of claim 1, wherein at least one of the first and second termini is tapered or shaped.

5. The stent of claim 1, further comprising a flange at one of the first and second termini.

6. The stent of claim 1, wherein at least one of the first and second termini has a diameter of about 1 mm to about 10 mm.

7. The stent of claim 6, wherein the diameter is about 1 mm to about 8 mm.

8. The stent of claim 1, wherein the first and second termini have different diameters.

9. The stent of claim 1, wherein the termini are located about 1 cm to about 5 cm apart.
10. The stent of claim 9, wherein the termini are located at about 1.5 cm to about 4 cm apart.
11. The stent of claim 10, wherein the termini are located about 2 cm to about 3 cm apart.
12. The stent of claim 1, wherein at least one of the first and second termini is sized for anastomotic insertion into a blood vessel of the patient.
13. The stent of claim 12, wherein the blood vessel is an artery.
14. The stent of claim 13, wherein the artery is a coronary artery.
15. The stent of claim 13, wherein the artery is the patient's aorta.
16. The stent of claim 12, wherein the blood vessel is a vein of the patient.
17. The stent of claim 1, further comprising a third terminus and a third opening at the third terminus, wherein the third opening is in fluid communication with the primary lumen through an intersecting lumen.
18. The stent of claim 17, wherein the primary and intersecting lumens intersect at a point closer to the first terminus than to the second terminus.
19. The stent of claim 17 wherein the primary and intersecting lumens intersect perpendicularly.

20. The stent of claim 17, wherein the primary and intersecting lumens intersect non-perpendicularly.

21. The stent of claim 1, wherein the material is resorbable by the patient in about a few minutes to about ten days.

22. The stent of claim 21, wherein the material is resorbable by the patient in about seven days to about ten days.

23. The stent of claim 21, wherein the material is resorbable by the patient in about one day to about seven days.

24. The stent of claim 23, wherein the material is resorbable by the patient in about one day to about two days.

25. The stent of claim 1, wherein the material comprises frozen physiologic saline.

28. The stent of claim 1, wherein the material is polyethylene glycol chemically conjugated to a naturally occurring compound.

29. The stent of claim 28, wherein the naturally occurring compound is a protein.

30. The stent of claim 29, wherein the protein is a collagenic material.

31. The stent of claim 30, wherein the collagenic material is a gelatin.

32. The stent of claim 30, wherein the collagenic material is selected from the group consisting of type I, type II, and type III collagens, and combinations thereof.

33. The stent of claim 28, wherein the naturally occurring compound is a polysaccharide.

34. The stent of claim 33, wherein the polysaccharide is selected from the group consisting of hyaluronic acid, cyclodextrin, hydroxymethylcellulose, cellulose ether, and starch.

35. The stent of claim 28, wherein the naturally occurring compound is a glycosaminoglycan or a proteoglycan.

36. The stent of claim 28, wherein the polyethylene glycol has a molecular weight of about 100 to about 20,000 daltons.

38. The stent of claim 1, wherein the material is a conjugate of collagen and a synthetic hydrophilic polymer.

39. The stent of claim 38, wherein the synthetic hydrophilic polymer is selected from the group consisting of polyethylene glycol and polyvinylpyrrolidone.

40. The stent of claim 1, further comprising a tissue sealant on a surface thereof.

41. A method of anastomosis comprising the steps of:

(a) inserting the first terminus of the stent of claim 1 through an aperture into the cavity of a physiologically functioning vessel of a patient, and the second terminus of the stent into a conduit, such that an interface is formed between the vessel and the conduit about the aperture; and

(b) attaching the vessel to the conduit at the interface.

42. A method of anastomosis comprising the steps of:

(a) inserting the first and second termini of the stent of claim 17 into a physiologically functioning vessel of a patient, and the third terminus of the stent into a bypass conduit, such that an interface is formed between the vessel and the bypass conduit about the aperture; and

(b) attaching the vessel to the bypass conduit at the interface.

43. The method of claim 42, wherein step (b) is carried out without need for a suture.

44. The method of claim 42, wherein step (b) comprises (b') introducing a tissue sealant around or over the interface between the vessel and the bypass conduit.

45. The method of claim 44, wherein the sealant comprises a collagenic material.

46. The method of claim 45, wherein the collagenic material comprises a methylated collagen.

47. The method of claim 45, wherein the collagenic material is selected from the group consisting of CIS, CSF, and combinations thereof.

48. The method of claim 44, wherein the sealant comprises a polyethylene glycol.

49. The method of claim 48, wherein the polyethylene glycol is selected from the group consisting of polyethylene glycol di-succinimidyl glutarate, pentaerythritol polyethylene glycol ether tetra-succinimidyl glutarate, pentaerythritol polyethylene glycol ether tetra-succinimidyl glutarate, polyethylene glycol mono-succinimidyl succinate, polyethylene glycol mono-succinimidyl propionic acid, polyethylene glycol mono-succinimidyl succinamide, polyethylene glycol di-succinimidyl succinamide, polyethylene glycol di-epoxide, polyethylene glycol di-isocyanate, polyethylene glycol di-carbonyldiimidazole, pentaerythritol polyethylene glycol ether tetra-maleimidopropionamide, pentaerythritol polyethylene glycol ether tetra-malimidopropionate, polyethylene glycol di-amine, diglycero polyethylene glycol ether tetra-amine, pentaerythritol polyethylene glycol ether tetra-amine, polyethylene glycol di-sulphydryl, pentaerythritol polyethylene glycol ether tetra-sulphydryl, pentaerythritol polyethylene glycol ether, diglycerol poly(ethylene glycol) ether, combinations thereof, and copolymers thereof.

50. The method of claim 44, wherein step (b) further comprises, after step (b'), (b'') crosslinking the sealant.

51. The method of claim 44, wherein the tissue sealant is injected around or over the interface.

52. The method of claim 44, wherein the tissue sealant is applied as a spray.

53. The method of claim 42, wherein steps (a) and (b) are carried out simultaneously.

Sub B1 54. A tissue plug for use in sealing an opening in a patient's tissue, comprising a solid object having a platen surface, which is adapted to cover the opening, contact the perimeter about the opening, or both; wherein the solid object is comprised of a non-polyglycolic acid material that is resorbable by the patient in a maximum of about 90 days.

55. The plug of claim 54, further comprising a tissue sealant on a surface thereof.

56. The plug of claim 54, wherein the platen surface is supported by a pedestal structure having a pedestal lateral dimension.

57. The plug of claim 56, wherein the platen surface has a lateral dimension equal to the pedestal structure lateral dimension.

58. The plug of claim 56, wherein the platen surface has a lateral dimension greater than the pedestal structure lateral dimension.

59. The plug of claim 54, wherein the platen surface is nonplanar.

60. The plug of claim 54, wherein the platen surface is shaped to conform to the lumen surface of a blood vessel of the patient.

61. The plug of claim 60, wherein the blood vessel is an artery.

62. The plug of claim 61, wherein the artery is a coronary artery.

63. The plug of claim 60, wherein the blood vessel is the patient's aorta.

Sub B2 64. The plug of claim 54, wherein ~~said~~ resorbable material is selected from the group consisting of saline, polyethylene glycol, and blood plasma.

65. The plug of claim 54, wherein the material is resorbable by the patient in about one day to about ten days.

66. The plug of claim 65, wherein the material is resorbable by the patient in about seven days to about ten days.

67. The plug of claim 65, wherein the material is resorbable by the patient in about one day to about seven days.

68. The plug of claim 67, wherein the material is resorbable by the patient in about one to about two days.

69. The plug of claim 54, wherein the material comprises a hydrophilic compound.

70. The plug of claim 69, wherein the hydrophilic compound comprises a polyethylene glycol-containing compound.

Sub B3 71. The plug of claim 70, wherein the polyethylene glycol-containing compound comprises a polyethylene glycol that is chemically conjugated with a naturally occurring compound.

72. The plug of claim 71, wherein the naturally occurring compound is a protein.

73. The plug of claim 72, wherein the protein is a collagenic material.

74. The plug of claim 73, wherein the collagenic material is a gelatin.

75. The plug of claim 73, wherein the collagenic material is selected from the group consisting of type I, type II, and type III collagens, and combinations thereof.

76. The plug of claim 71, wherein the naturally occurring compound is a polysaccharide.

77. The plug of claim 76, wherein the polysaccharide is selected from the group consisting of hyaluronic acid, cyclodextrin, hydroxymethylcellulose, cellulose ether, and starch.

78. The plug of claim 71, wherein the naturally occurring compound is a glycosaminoglycan or a proteoglycan.

Sub B4 79. The plug of claim 70, wherein the polyethylene glycol has a molecular weight of about 100 to about 20,000 daltons.

80. The plug of claim 69, wherein the hydrophilic material is a collagenic material.

Sub B5 81. The plug of claim 80, wherein the collagenic material comprises a collagen that is chemically conjugated to a synthetic hydrophilic polymer.

82. The plug of claim 81, wherein the synthetic hydrophilic polymer is selected from the group consisting of polyethylene glycol and polyvinylpyrrolidone.

83. A method of sealing an opening in a patient's tissue comprising the steps of:

(a) positioning the plug of claim 54 in relationship to an opening in a patient's tissue, such that the plug covers the opening, contacts the perimeter about the opening, or both, thereby forming an interface between the plug and the tissue; and

(b) adhering the patient's tissue to the plug to form a closure.

84. The method of claim 83, wherein step (b) comprises (b') introducing a tissue sealant around or over the interface.

85. The method of claim 84, wherein the sealant comprises a collagenic material.

86. The method of claim 85, wherein the collagenic material is a PEG-collagen.

87. The method of claim 84, wherein the sealant comprises polyethylene glycol.

88. The method of claim 84, wherein step (b) further comprises, after step (b'), (b'') crosslinking the sealant.

89. The method of claim 84, wherein the tissue sealant is applied through injection.

90. The method of claim 84, wherein the tissue sealant is applied as a spray.

91. The method of claim 83, wherein steps (a) and (b) are carried out simultaneously.

92. The method of claim 83, further comprising, after step (a), (b') placing additional tissue in contact with the plug, such that the plug is interposed between the additional tissue and the tissue associated with the opening.

93. The method of claim 92, further comprising, after (b'), adhering the additional tissue to the tissue associated with the opening.

Sub Bb
~~94. A sutureless method of anastomosis comprising the steps of:
(a) providing a stent comprising a first terminus, a second terminus, a third terminus, and an opening at each terminus that fluidly communicate with each other through the interior of the stent, wherein the stent is comprised of a non-polyglycolic acid material that is resorbable by a patient in up to about 90 days;~~

*Sub B6
cont.* (b) inserting the first and second termini of the stent through an aperture into a cavity of a physiologically functioning vessel of a patient, and the third terminus of the stent into a bypass conduit, such that an interface is formed between the vessel and the bypass conduit about the aperture; and

(c) applying a tissue sealant at the interface to attach the conduit to the vessel.

95. A sutureless method of sealing an opening in a patient's tissue comprising the steps of:

(a) providing a plug comprised of a solid non-polyglycolic acid material that is resorbable by the patient in a maximum of about 90 days;

(b) positioning the plug in relationship to an opening in a patient's tissue, such that the plug covers the opening, contacts the perimeter about the opening, or both, thereby forming an interface between the plug and the tissue; and

(c) applying a resorbable sealant at the interface to form a closure.

96. A sutureless method of anastomosis comprising the steps of:

(a) providing a stent comprising a first terminus, a second terminus, a third terminus, and an opening at each terminus that fluidly communicate with each other through the interior of the stent, wherein the stent is comprised of material that is resorbable by a patient in up to about 90 days;

(b) inserting the first and second termini of the stent through an aperture into a cavity of a physiologically functioning vessel of a patient, and the third terminus of the stent into a bypass conduit, such that an interface is formed between the vessel and the bypass conduit about the aperture; and

(c) applying a tissue sealant at the interface to attach the conduit to the vessel such that the interface exhibits a tensile strength of at least about 1.3N/cm^2 .